DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

December 22, 1998

99-PHI-09

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert Weikert
Weikert's Livestock Inc.
P.O. Box 707
Carrolls Tract Road
Fairfield, Pennsylvania 17320

Dear Mr. Weikert:

On April 8, 1998, your cattle dealing business, located in Fairfield, Pennsylvania was visited by Food and Drug Administration (FDA) Investigator Gregory E. Beichner in response to United States Department of Agriculture (USDA) reports regarding an illegal drug residues cows you purchased and delivered for sale and slaughter for human food. Additional investigation by the FDA at the slaughterhouse, [redacted], has revealed serious violation of Section 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about March 30, 1998 your firm purchased a medicated cow identified with back tag #1061 from [redacted] and delivered the animal for slaughter as human food at [redacted] The animal was slaughtered at this facility on or about March 31, 1998. United States Department of Agriculture (USDA) analysis of tissue samples collected from the animal identified the presence of 0.75 ppm (parts per million) gentamicin in the kidney tissue. Gentamicin is not approved for use in dairy cattle, and therefore, there is no tolerance for the presence of this drug edible bovine tissue. The presence of gentamicin in edible tissue from this animal at the above concentration level causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

FDA inspection at [redacted] on July 16, 1998 revealed that your firm received a weight ticket for the cow,

back tag, #1061, dated 3/30/98, which indicates that the animal was medicated.

On or about March 26, 1998 your firm purchased a cow identified with back tag #6826 from Pen #101 at [redacted] and delivered the animal for slaughter as human food at [redacted] The animal was slaughtered at this facility on or about March 30, 1998. USDA analysis of tissue samples collected from the animal identified the presence of 1.20 ppm gentamicin in the kidney tissue. The presence of gentamicin in edible tissue from this animal at the above concentration level causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

On or about August 12, 1997 you purchased a medicated cow identified with back tag #9092 from [redacted] and delivered the animal for slaughter as human food at [redacted] The animal was slaughtered at this facility on or about August 13, 1997. USDA analysis of tissue samples collected from the animal identified the presence of 1.20 ppm gentamicin in the kidney tissue. The presence of gentamicin in edible tissue from this animal at the above concentration level causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

FDA inspection at [redacted] on April 9, 1998 revealed that medicated animals are identified with "Red Tags" and that such animals are announced and sold at auction as medicated. Our inspection revealed that your firm's [redacted] dated August 12, 1997 indicates that the animal with back tag #9092 was identified as a "Red Tag" animal.

On or about June 3, 1997 you purchased a cow identified with back tag #5097 from Pen #101 at [redacted] and delivered the animal for slaughter as human food at [redacted] The animal was slaughtered at this facility on or about June 3, 1997. USDA analysis of tissue samples collected from this animal identified the following violative drug residues: 0.06 ppm penicillin in the kidney tissue, 2.8 ppm sulfadimethoxin in the liver tissue, and 3.0 ppm sulfadimethoxin in the muscle tissue. The tolerance for penicillin in edible portions of bovine tissue is 0.05 ppm; the tolerance for sulfadimethoxin in edible portions of bovine tissue is 0.10 ppm. The presence of these drugs in edible tissue from this animal at the above-referenced concentration levels causes the food to be adulterated under Sections 402(a)(2)(C)(ii) of the Act, because it contains a new animal drug that is unsafe within

the meaning of Section 512.

On or about June 25, 1997 you purchased a medicated cow identified with ear tag #30 and back tag #2616 from [redacted] and delivered the animal for slaughter as human food at [redacted] The animal was slaughtered at this facility on or about June 26, 1997. USDA analysis of tissue samples collected from the animal identified the presence of 1.30 ppm penicillin in the kidney tissue. The tolerance for penicillin in edible portions of bovine tissue is 0.05 ppm. The presence of penicillin in edible tissue from this animal at the above concentration level causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

FDA inspection at [redacted] on April 9, 1998 revealed that [redacted], and [redacted] are subdivisions or branches of the same firm, [redacted]. The inspection revealed that medicated animals at these auction facilities are identified with "Red Tags" and such animals are announced and sold at auction as medicated. Our inspection of your firm on April 8, 1998 revealed that your firm's [redacted] Invoice dated June 25, 1998 indicates that the animal with ear tag #30 was identified as a "Red Tag" animal.

On or about April 24, 1997 you purchased a cow identified with back tag #2326 from Pen #101 at [redacted] and delivered the animal for slaughter as human food at [redacted] The animal was slaughtered at this facility on or about April 25, 1997. USDA analysis of tissue samples collected from the animal identified the presence of 668 ppm neomycin in the kidney tissue. The tolerance for neomycin in edible portions of bovine tissue is 0.75 ppm. The presence of neomycin in edible tissue from this animal at the above concentration level causes the food to be adulterated under Section 402(a)(2)(C)(ii) of the Act, because it contains a new animal drug that is unsafe within the meaning of Section 512.

FDA inspection at [redacted] on October 1998 revealed that Pen #100, #101, #312, and #312a are used to sell "As Is" animals. Animals sold from these pens are, in general, in poor condition whose disease condition and medication status is suspect. As a result, it is your responsibility to request information regarding the medication status of such animals to determine their acceptability for slaughter for human food.

Our investigation found that you purchase and hold animals under conditions that permit animals bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for assuring that animals offered for sale for slaughter for food have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated.
You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

The violations listed above are not intended to be all-inclusive. It is your responsibility to assure that your operation is in compliance with the law. As a livestock dealer, purchaser, or hauler of animals, you are frequently the individual who introduces or offers for introduction into interstate commerce, adulterated animals ("food" under the Act). As such, you share responsibility for violating the Federal Food, Drug, and Cosmetic Act. To avoid future illegal residue violations you should take precautions such as:

1) implementing a system to determine from the source of these animals whether the animals have been medicated and with what drug(s); and,

2) if the animals have been medicated, implementing a system to withhold the animals from slaughter for an appropriate period of time to deplete potentially hazardous residues of drugs from edible tissues. If you do not want to hold the medicated animals, then they should not be offered for human food, and they should be clearly identified and sold as a medicated animal.

The FDA is aware of your firm's history/practice of purchasing medicated cows from the medicated pen at [redacted]. Inspections by the Food and Drug Administration at [redacted] in October 1995 and December 1995 revealed that between January 20, 1992, and September 29, 1995, your firm purchased in approximately 97 cows from the medicated pen at [redacted]

During an FDA inspection of your firm on December 19, 1995 Jeffery L. Weikert indicated that medicated cows that were purchased from [redacted] were held on the Weikert farm for 30 to 120 days. This inspection revealed that these cows were not be traceable to [redacted] medicated pen at the slaughterhouse because Weikert Livestock did not maintain their identity. Weikert Livestock

retagged these cows with their own tag numbers prior to delivery for slaughter. Animal identification must be maintained so that FDA investigators can trace back animals found with violative drug residues as far back as in the chain of handling as possible. As a result, responsibility for the referenced 97 animals purchased rests with your firm since traceback to the producer would not be possible.

Additionally, Jeffery L. Weikert stated during the 1995 inspection that [redacted] did not provide the medication status of the cows purchased from their medicated pen. Without having this information it would be impossible to know how long to hold the subject cow prior to offering it for slaughter for human food. It is therefore incumbent on livestock dealers to request the medication status of animals purchased as "medicated" or "as is" so that these animals can be withheld form slaughter for the proper period of time.

Please note that it is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that animals were knowingly purchased from a medicated pen or an "as is" pen for your account and the animals were sold to a slaughterhouse that ships beef in interstate commerce, is enough to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen (15) working days, state the reasons for the delay and the timeframe in which correction will be achieved. Please include copies of any available documentation demonstrating that correction has been accomplished.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Sincerely yours,

W. Charles Becoat
Acting District Director
Philadelphia District

jci

cc: Dr. John I. Enck, Director
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PA Department of Agriculture
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cc: USDA, FSIS, FO, Technical Service Center
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